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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/460,292	12/10/1999	David J. Mangelsdorf	UTSD:596	2313

7590

09/25/2003

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EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

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DATE MAILED: 09/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/460,292

Applicant(s)

MANGELSDORF ET AL.

Examiner

Joseph T. Voitach

Art Unit

1632

--Th MAILING DATE of this communication app ars on th cov r sheet with th correspondence address --

THE REPLY FILED FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☒ A Notice of Appeal was filed on 14 July 2003. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

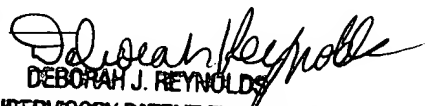
Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 1,2,4-14,21,23-27,29,44 and 45.

Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s).
10. ☐ Other: _____


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Continuation of 2. NOTE: the amendment to recite the LXRalpha 'polypeptide' can not respond to dietary cholesterol raises new issues under 35 USC 112, first paragraph regarding enablement and written description for such a peptide as supported by the instant specification. Further, Applicants do not point to any specific support for the amendment raising consideration of new matter..

Continuation of 5. does NOT place the application in condition for allowance because: To the extent that Applicants' arguments apply to the instantly pending claims, Examiner agrees that the specification enables use of both heterozygous and homzygous alterations. However, it is only the disruption(s) of the LXR gene which results in a decreased amount of the LXRalpha protein which produce the enabled and usable phenotype. Additionally, Examiner would agree that any phenotype resulting from decreased expression of LXRalpha would be inherent to said transgenic mouse, however the only particular phenotypes provided for use in the present specification are cholesterol accumulation, increased bile acid synthesis and hepatomegaly. To this end, the methods drawn to these phenotypes would be fully enabled, however are subject to rejection because the breadth of the mouse provided as a starting material. The present disclosure provides for the correlation between decreased amounts of the LXRalpha protein and specific particular phenotypes in transgenic mice, however fails to provide adequate support for any alteration and any possible phenotype resulting therefrom .